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Title:	SYSTEM, KIT, AND METHOD FOR MEASURING MEMBRANE DIFFUSION		

BRIEF ON APPEAL

Mail Stop: Appeal Brief-Patents
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October 11, 2007 Zontelli

Date Signed by: Angela M. Zontelli

Dear Sir:

This is an appeal from the Office Action mailed on 05/16/2007 finally rejecting claims 1-18, 20, 42, 43, and 45.

Fees

☒ Any required fee under 37 CFR § 41.20(b)(2) will be made at the time of submission via EFS-Web. In the event fees are not or cannot be paid at the time of EFS-Web submission, please charge any fees under 37 CFR § 1.17 which may be required to Deposit Account No. 13-3723.

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A Notice of Appeal in this application was mailed on 08/15/2007, and was received in the USPTO on 08/15/2007.

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REAL PARTY IN INTEREST

The real party in interest is 3M Company (formerly known as Minnesota Mining and Manufacturing Company) of St. Paul, Minnesota and its affiliate 3M Innovative Properties Company of St. Paul, Minnesota.

RELATED APPEALS AND INTERFERENCES

Appellants are unaware of any related appeals or interferences.

STATUS OF CLAIMS

Claims 1-18, 20, 37, 38, 42, 43, and 45 are pending. Claims 37-38 are withdrawn. Claims 19, 21-36, 44, and 46 are canceled.

Claims 1-18, 20, 42, 43, and 45 stand finally rejected.

Applicant notes that although the Office Action Summary page of the Office Action dated 5/16/2007 (which includes the final rejection being currently appealed) does not list withdrawn claims 37 and 38, they were included in the claim listing included on page 2 of Applicant's Amendment and Response dated Feb. 28, 2007. Accordingly, it is believed that claims 37 and 38 are pending and withdrawn.

The final rejection of claims 1-18, 20, 42, 43, and 45 is being appealed.

STATUS OF AMENDMENTS

No amendments have been filed after the final rejection.

SUMMARY OF CLAIMED SUBJECT MATTER

Finally rejected claim 1 concerns a system for measuring diffusion of a compound across a membrane. An exemplary embodiment of the system is illustrated in Fig. 1. For convenience, Fig. 1 is reproduced below:

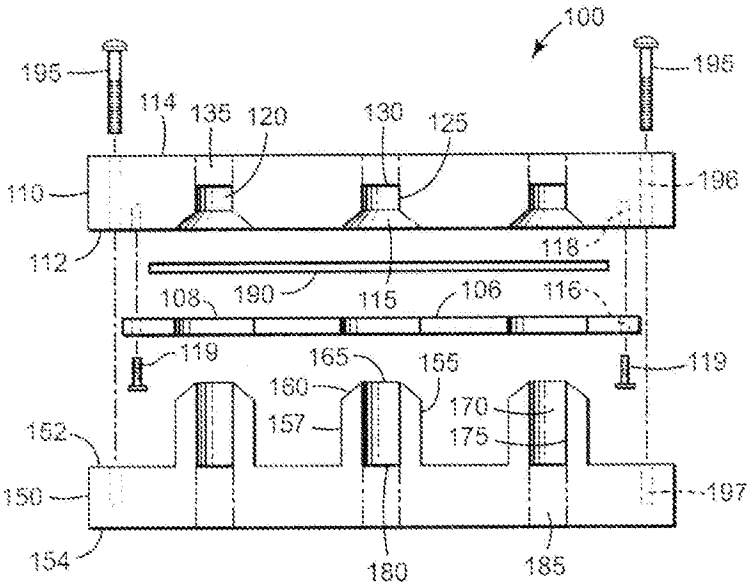

FIG. 1

Corresponding discussion of Fig. 1 (and hence the invention of claim 1) may be found in the specification, for example, on page 4, line 16 through page 5, line 15. Specific structure for the §112 means clauses in claim 1 (i.e., the "first fastening means" and "second fastening means") may be found in the specification, for example, on page 7, lines 17 to 26.

Briefly, in one aspect the invention concerns a system (100) for measuring diffusion of a compound across a membrane. The system has a first base (150) having first and second opposed surfaces (152, 154) and having a plurality of hollow projections (155) extending outwardly from the first surface (152). Each hollow projection (155) has a tapered tip (160) with an opening (165) therein and a respective cavity (170) contiguous with the opening (165) disposed within the projection (155). A second base (110) has first and second opposed surfaces (112, 114). The first surface (112) of the second base (110) has a plurality of recessed tapered openings (115) therein adapted to engage the plurality of hollow projections (155). Each recessed tapered opening (115) is contiguous with a respective cavity (120) that extends into the

second base (110). Membrane (190) contacts the recessed tapered openings (115) and the tips (16) of the hollow projections (155). The first base (150) is fastened to the second base (110) by a first fastening means (shown in Fig. 1 as screws (195) which pass through holes (196) and engage threaded holes (197)). A retaining plate (106) has perforations (108) therein adapted to allow the hollow projections (155) to pass therethrough, is fastened to the second base (110) by a second fastening means (shown in Fig. 1 by screws (119), which pass through holes (116) in retaining plate (106) and engage threaded holes (118) in second base 110), wherein the membrane (190) is disposed between the second base (110) and the retaining plate (106). The retaining plate (106) allows *inter alia* for the first base to be unfastened from the second base-membrane-retaining plate subassembly and refastened without changes in membrane position and/or the need to refill cavities in the second base with liquid (e.g., see the specification on page 5, lines 16-22).

The invention claimed in claim 1 includes three alternative embodiments: a) each cavity (170) within a hollow projection (155) extends through the first base (150) and forms an opening at the second surface (154) of the first base (150); b) each cavity (120) within the second base (110) extends through the second base (110) and forms an opening at the second surface (114) of the second base (110); or c) each cavity (170) within a hollow projection (155) extends through the first base (150) and forms an opening at the second surface (154) of the first base (150), and each cavity (170) within the second base (110) extends through the second base (100) and forms an opening at the second surface of the second base (100).

Independent claim 42 is directed to a system, in kit form, for holding a membrane. Elements of the kit, if assembled, correspond generally to the system (100) shown in Fig. 1 and discussed above, except that the system is in kit form and does not require a membrane (190).

Discussion of the system in kit form of claim 42 may be found in the specification, for example, on page 4, line 16 through page 5, line 15 and on page 10, lines 12 to 13. Structure for the §112 means in claim 42 (i.e., "means for fastening the first base to the second base" and "means for fastening the retaining plate to the second base") may be found in the specification, for example, on page 7, lines 17-26.

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

First Ground of Rejection

Claims 1-18, 20, 42,43,45 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Mak et al. (U. S. Pat. No. 5,490,415) in view of Bennett, Jr. et al. (U. S. Pat. No.4,511,534).

Second Ground of Rejection

Claims 1-18,20,42,43,45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mak et al. (U. S. Pat. No. 5,490,415) in view of Grass (U. S. Pat. No. 5,591,636).

ARGUMENT

First Ground of Rejection

Claims 1-18, 20, 42, 43, and 45 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Mak et al. (U. S. Pat. No. 5,490,415) in view of Bennett, Jr. et al. (U. S. Pat. No. 4,511,534).

Regarding Claim 1, the Examiner alleges that Mak teaches a diffusion test apparatus that comprises a first base (22) having a plurality of hollow projections (30) extending outwardly from a first surface (1 2), each hollow projection having a tapered tip (Fig. 2 of Mak, ref. 26) with an opening (28) therein and a respective cavity contiguous with the opening disposed within the projection (Fig.2 of Mak); a second base (36) having a first surface having a plurality of recessed tapered openings therein adapted to engage the plurality of hollow projections; a membrane contacting the recess tapered openings and the tips of the hollow projections, the first base being fastened to the second base by fasteners (14) which are removable when the membrane is changed. The Examiner further alleges that the hollow projections of Mak extend through the first base and forms an opening at the second surface of the first base (Fig. 2 and 3 of Mak).

The Examiner concedes that Mak does not teach a retaining plate for retaining the membrane to the second base.

The Examiner alleges that "Bennett teaches a liquid transfer device that comprises a second base 32 and a retaining plate 42 [sic] which holds a membrane to the second base 32 by removable fasteners 42 (figs. 2-4 of Bennett)." The Examiner further alleges that Bennett provides this configuration for quick and easy movement of liquid from one container to the next.

The Examiner argues that it would have been obvious to one having an ordinary skill in the art at the time of the invention of modify Mak et al. to employ a retaining plate to hold the membrane to the second base (4) to allow for easy removal of the second base and membrane together in order to gain access to the diffused liquid in the first base (6) in one step, thereby reducing the number of steps a user would incur to gain access to the diffused liquid and decrease fumbling around with expired membrane (contaminated) being separate from the second base. Finally, the Examiner alleges that Mak is only interested in the diffused liquid that remains in the

first base (6) as seen in col. 3, lines 45-49, because the sample is thereafter analyzed by conventional scintillation countering techniques.

Claims 1-18, and 20

Applicants submit that the liquid transfer device of Mak et al. is explicitly intended for single use. For example, Mak et al. state in col. 3, lines 30-50:

> "A wide variety of diffusional systems have been developed for use with rate limiting membranes. Typically, the systems have cells arranged in either a side-by-side or vertical configuration and provide a means for agitating the cell chambers. For a review of conventional diffusion cell designs, see Friend, D. R., Journal of Controlled Release, 1992, 18, 235-248. With prior art permeation study testing procedures, the diffusion test is typically run for a period of 24 hours or more; over the course of the study, samples are periodically withdrawn from the receiver receptacle to evaluate the flux of drug through the skin over time. Conventional flowthrough diffusion cells are of this type. In contrast, the present invention is designed so that the permeation experiment is run to a pre-determined end point, such as six hours. Upon termination of the diffusion experiment, the receiver assembly is detached from the donor assembly. The receiver samples are then withdrawn from their respective wells, typically by aspiration, and assayed by an appropriate analytical method. The length of the permeation experiment may be varied by the user." [underlining added]

Further teaching of single experiment usage may be found in Mak et al. in col. 5, lines 24-29. In view of the above, it is clear that Mak et al. do not contemplate replacement of the receiver assembly during experimentation. Moreover, Mak et al. affirmatively teach that the device is to be used with only one receiver assembly, thereby teaching away from combining the retaining plate of Bennett, Jr. et al. with the diffusion test apparatus of Mak et al. Accordingly, adding a retaining plate to the device of Mak et al. would have no purpose and would add unneeded complexity.

In the Response to Remarks section of the Office Action mailed on 05/16/2007 the Examiner argues that it would have been obvious to one having an ordinary skill in the art at the time of the invention of modify Mak et al. to employ a retaining plate to hold the membrane to the second base (4) to allow for easy removal of the second base and membrane together in order to gain access to the diffused liquid in the first base (6) in one step, thereby reducing the number

of steps a user would incur to gain access to the diffused liquid and decrease fumbling around with expired membrane (contaminated) being separate from the second base.

Such reasoning is derived from hindsight based on Applicants' own disclosure, for example, since neither Mak et al. nor Bennett, Jr. et al. do not identify any desirability of retaining the membrane in contact with the second base or a problem with handling the membrane during disassembly. Even assuming *arguendo*, and without conceding that such is the case, that removal of the membrane created some minor inconvenience, common sense dictates that it would clearly not rise to the level of extra effort created by fabricating a suitable retaining plate and mounting the membrane using the retaining plate as in claim 1, and hence there is no proper reason to do so.

Moreover, Mak et al. and Bennett, Jr. et al. are from different fields of endeavor. For example, Mak et al. concerns a diffusion test apparatus designed to study diffusion of material across a membrane while Bennett, Jr. et al. concerns a liquid transfer device (essentially an array of pipettes) wherein diffusion of material through the membrane would be at least undesirable. Further, any alleged teaching by Bennett, Jr. et al. to provide such a configuration for quick and easy movement of liquid from one container to another does not relate to diffusion experiments, but merely to pipetting-type operations.

For at least these reasons, it is submitted that no teaching, motivation, or suggestion or other proper grounds has been provided to combine Mak et al. with Bennett, Jr. et al., absent impermissible hindsight based on Applicants' own disclosure, and that the final rejection of claim 1 should be reversed.

Claim 1 is patentable for the reasons given above. Claims 2-18, and 20 each add additional features to patentable claim 1. Hence, claims 2-18, and 20 are likewise patentable.

Claims 42, 43, and 45

The above arguments regarding claim 1 also apply to claim 42 by analogy to the arguments.

For at least these reasons, it is submitted that no teaching, motivation, or suggestion has been provided to combine Mak et al. with Bennett, Jr. et al., absent impermissible hindsight based on Applicants' own disclosure, and that the final rejection of claim 42 should be reversed.

Claim 42 is patentable for the reasons given above. Claims 43 and 45 each add additional features to patentable claim 42. Hence, claims 43 and 45 are likewise patentable.

Conclusion

In summary, the final rejection of claims 1-18, 20, 42, 43, and 45 under 35 U.S.C. § 103(a) as being unpatentable over Mak et al. in view of Bennett, Jr. et al. should be reversed.

Second Ground of Rejection

Claims 1-18,20,42,43,45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mak et al. (U. S. Pat. No. 5,490,415) in view of Grass (U. S. Pat. No. 5,591,636).

The Examiner characterizes Mak et al. essentially as in the first ground of rejection.

The Examiner alleges that Grass teaches a membrane holder that comprises an upper base 14, a retaining plate 18 and a lower base 16, and a membrane placed between the upper base and the retaining plate 18 and held together by means of a threaded connection between the upper base and the retaining plate (col. 3, lines 44-50). The Examiner further alleges that the retaining plate is attached to the base plate by bolts 20.

The Examiner argues that it would have been obvious to one having an ordinary skill in the art at the time of the invention to modify Mak et al. to employ a retaining plate to hold the membrane to the second base (4) to allow for easy removal of the second base and membrane together in order to gain access to the diffused liquid in the first base (6) in one step, because this would reduce the number of steps a user would incur to gain access to the diffused liquid and decrease fumbling around with expired membrane (contaminated) being separate from the second base. The Examiner alleges that Mak et al. is only interested in the diffused liquid that remains in the first base (6) as seen in col. 3, lines 45-49 because the sample is thereafter analyzed by conventional scintillation countering techniques. Finally, the Examiner again alleges that Mak et al. are only interested in the diffused liquid that remains in the first base for reasons as discussed above.

Claims 1-18, and 20

As discussed in response to the rejection over Mak et al. in view of Bennett, Jr. et al. above, Applicants submit that Mak et al. teach away from using a retaining plate.

Moreover, the retaining plate of Grass (e.g., see Grass in Fig. 2) fails to teach, motivate, or properly suggest a configuration wherein perforations in the retaining plate are adapted such that the hollow projections pass therethrough as in claim 1.

For at least these reasons, it is submitted that no proper teaching, motivation, or suggestion exists to combine Mak et al. with Grass, absent impermissible hindsight based on Applicants' own disclosure, and that the final rejection of claim 1 should be reversed.

Claim 1 is patentable for the reasons given above. Claims 2-18, and 20 each add additional features to patentable claim 1. Hence, claims 2-18, and 20 are likewise patentable.

Claims 42, 43, and 45

The above arguments regarding claim 1 also apply to claim 42 by analogy to the arguments.

Conclusion

In summary, the final rejection of claims 1-18, 20, 42, 43, and 45 under 35 U.S.C. § 103(a) as being unpatentable over Mak et al. in view of Grass should be reversed.

CONCLUSION

For the foregoing reasons, appellants respectfully submit that the Examiner has erred in rejecting this application. Please reverse the Examiner on all counts.

Respectfully submitted,

Oct. 10, 2007
Date

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CLAIMS APPENDIX

1. (previously presented) A system for measuring diffusion of a compound across a membrane comprising:

a first base having first and second opposed surfaces and having a plurality of hollow projections extending outwardly from the first surface, each hollow projection having a tapered tip with an opening therein and a respective cavity contiguous with the opening disposed within the projection;

a second base having first and second opposed surfaces, the first surface of the second base having a plurality of recessed tapered openings therein adapted to engage the plurality of hollow projections, each recessed tapered opening being contiguous with a respective cavity that extends into the second base;

a membrane contacting the recessed tapered openings and the tips of the hollow projections, wherein the first base is fastened to the second base by a first fastening means, and wherein: a) each cavity within a hollow projection extends through the first base and forms an opening at the second surface of the first base; or b) each cavity within the second base extends through the second base and forms an opening at the second surface of the second base; or c) each cavity within a hollow projection extends through the first base and forms an opening at the second surface of the first base, and each cavity within the second base extends through the second base and forms an opening at the second surface of the second base; and

a retaining plate having perforations therein adapted to allow the hollow projections to pass therethrough, wherein the retaining plate is fastened to the second base by a second fastening means, wherein the membrane is disposed between the second base and the retaining plate.

2. (original) The system of claim 1, wherein at least a portion of at least the first or second base is transparent or translucent.

3. (original) The system of claim 1, wherein the first fastening means is a removable means.

4. (original) The system of claim 1, wherein each cavity within a hollow projection extends through the first base and forms an opening at the second surface of the first base.

5. (original) The system of claim 4, further comprising a first covering means fastened to the second surface of the second base.

6. (original) The system of claim 1, wherein the cavity in each hollow projection extends into the first base.

7. (original) The system of claim 1, wherein the cavity in each hollow projection extends through the second base and forms an opening at the second major surface of the second base.

8. (original) The system of claim 1, further comprising a cover plate fastened to the second surface of the first base.

9. (original) The system of claim 8, wherein at least a portion of the cover plate is transparent or translucent.

10. (original) The system of claim 1, wherein the first and second surfaces of at least one of the first and second bases are major surfaces.

11. (original) The system of claim 1, wherein at least one of the first and second bases comprises a plate.

12. (original) The system of claim 1, wherein each tapered tip has a cross-sectional profile that comprises at least one of an arcuate portion or a beveled portion.

13. (original) The system of claim 1, wherein each recessed tapered opening has a cross-sectional profile that comprises at least one of an arcuate portion or a beveled portion.

14. (original) The system of claim 1, wherein the projections further comprise a body portion having at least one wall.

15. (original) The system of claim 14, wherein the body portion is cylindrical.

16. (original) The system of claim 1, wherein the membrane comprises a synthetic polymer.

17. (original) The system of claim 1, wherein the membrane comprises animal tissue.

18. (original) The system of claim 1, wherein the membrane comprises skin.

19. (canceled)

20. (previously presented) The system of claim 1, wherein the second fastening means is removable.

Claims 21 - 36. (canceled)

37. (withdrawn) A method of measuring diffusion of a compound through a membrane comprising:

providing a system according to claim 1;

placing a first fluid composition into at least one cavity in the first base;

placing a second fluid composition comprising a compound into at least one cavity in the second base, wherein the cavities in the first and second bases are in fluid communication through the membrane; and

analyzing the compound content of the first fluid composition.

38. (withdrawn) A method of measuring diffusion of a compound through a membrane comprising:

providing a system according to claim 4;

placing a first fluid composition into at least one cavity in the first base;

placing a second fluid composition comprising a compound into at least one cavity in the second base, wherein the cavities in the first and second bases are in fluid communication through the membrane; and

analyzing the compound content of the first fluid composition.

Claims 39-41. (canceled)

42. (previously presented) A system, in kit form, for holding a membrane comprising:

a first base having first and second opposed surfaces and having a plurality of hollow projections extending outwardly from the first surface, each hollow projection having a tapered tip with an opening therein and a respective cavity contiguous with the opening disposed within the projection;

a second base having first and second opposed surfaces, the first surface having a plurality of recessed tapered openings therein adapted to engage the plurality of hollow projections, each recessed tapered opening being contiguous with a respective cavity that extends into the second base;

means for fastening the first base to the second base wherein: a) each cavity within a hollow projection extends through the first base and forms an opening at the second surface of the first base; or b) each cavity within the second base extends through the second base and forms an opening at the second surface of the second base; or c) each cavity within a hollow projection extends through the first base and forms an opening at the second surface of the first base, and each cavity within the second base extends through the second base and forms an opening at the second surface of the second base;

a retaining plate having perforations therein adapted to allow the hollow projections to pass therethrough; and

means for fastening the retaining plate to the second base.

43. (original) The system of claim 42, wherein each cavity within a hollow projection extends through the first base and forms an opening at the second surface of the first base.

44. (canceled)

45. (original) The system of claim 42, wherein each cavity within the second base extends through the second base and forms an opening at the second surface of the second base.

46. (canceled)

EVIDENCE APPENDIX

None.

RELATED PROCEEDINGS APPENDIX

None.